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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/046,526	01/10/2002	Guoqing Chen	A-735A	3463

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U.S. Patent Operations/JWB
Dept. 4300, M/S 27-4-A
AMGEN INC.
One Amgen Center Drive
Thousand Oaks, CA 91320-1799

EXAMINER	
PATEL, SUDHAKER B	

ART UNIT	PAPER NUMBER
1624	12

DATE MAILED: 11/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/046,526	CHEN ET AL.	
	Examiner	Art Unit	
	Sudhaker B. Patel, D.Sc.Tech.	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 July 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-8,10-14 and 16-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-4,8,10-14 and 16-42* is/are rejected.

7)☒ Claim(s) *6 and 7* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *11*.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicants' communication paper # 10 dated 10/9/03 is acknowledged.

Applicants have cancelled claims 5,9,15, amended claims 1-4,6-8,10-12,14,16-17, and presented new claims 18-42. Therefore, the claims in this application are the claims 1-4,6-8,10-14,16-42.

After further review and consideration, this application is found not ready for allowance for the reasons stated bellow.

Election/Restrictions

1. Applicant's election of invention of Group II without traverse in Paper No. 8 dated 6/11/03 had been acknowledged by previous Office communication, and restriction/election had been made FINAL in Office Action Paper # 9 dated 7/10/03.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 10/9/03 as paper # 11. is being considered by the examiner. Signed copy of the PTO Form 1449 is enclosed with this communication for applicants' record.

4. **Rejection withdrawn:** Applicants' arguments and remarks have been considered and found persuasive for the withdrawal of DP rejection against co-pending U.S.Application Sr. No. 10197960. See allowable subject matter bellow. Accordingly, the DP rejections are now withdrawn.

5. However, applicants' request for allowing the reference application '960 and the instant application to be issued on the same day, is not found persuasive, because the

examiner cannot do so for many reasons. e.g. the cases are handled according to the filing dates of the applications, and amendments are being attended to within 1 month of date of docketing to examiner. Examiner has no control over the issuing date for a patent.

6. **Rejections with drawn:** Applicants' cancellation of claims, and various amendments to claims as stated earlier make the rejections made under 35 U.S.C. 102(a) moot. Therefore, rejection made against Schindler et al (WO 2000002851) are now withdrawn.

7. **Rejections maintained:** Applicants' argument and remarks have been considered, but not found persuasive for withdrawal of Rejections) made under 35 U.S.C. 112 paragraph second. Therefore, the same are maintained further for the reasons already stated in earlier Office Action paper # 9 dated 7/10/03 for claims 1-4,8,10,11. Applicants state that the definition of: "a pharmaceutically acceptable derivatives" has been recited in page 41 of the specification. Correction to claims as:" A compound or pharmaceutically acceptable salt or ester thereof" is required.

7A. **New Rejections:** Claim 18 is rejected under 35 U.S.C. 112, second paragraph, because it recites:" a compound and pharmaceutically acceptable salts thereof". Correction to:" a compound or pharmaceutically acceptable salts thereof:" is required.

New Rejections/Objections:

Claim Objections

8. Claims 6, 7 are objected to under 37 CFR 1.75 as being a substantial duplicate of claim 1. When two claims in an application are duplicates or else are so close in

content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

9. Claim 13 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim contains method of treating cancer with a complex mixture of a pharmaceutical composition of compound(s) of claim 1 with additional compound(s) consisting of subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claim remains silent about the exact chemical or agent, which could be antibiotic, alkylating agents, antimetabolite agents, hormonal agents, immunological agents, interferon-type agents and miscellaneous agents. The claim does not disclose the exact mode or step or process of administration, the exact dosage requirement, and the exact form of the compound or agent either as pharmaceutically acceptable salt(s) or a prodrug, and the exact nature of a subject.

10. **Rejections maintained:** Claims 12,14,16,17, 19-42 related to generic method of treatment of proliferation-related disorders and cancer are rejected under 35 U.S.C. 112 first paragraph for the reasons already stated in earlier Office Action paper # 9 dated 7/10/03. Therefore, the rejections are maintained further.

Applicants have recited MPEP 2164.02-2164.05. However, these guidelines are not exactly for the pharmaceutical drugs.

Applicants are urged to refer to MPEP 2107.03 for the utility requirement under 35 U.S.C. 112, first paragraph, in drug cases.

11. Examiner appreciates for the various literature references provided to support the method of use for the instant compounds.

The references do not deal with the chemical compounds having similar structure(s). e.g. Hennequin et al (J.Med. Chem., 42,5369-89(1999)) deals with chemistry of derivatives of **Anilinoquinazolines** (see Fig. 1 in page 1370, and compounds in Table 1 in page 5371 which are not in any way similar to instantly claimed compounds which have a core:" ***2-amino-pyridine-3-carboxylic acid amide***". Therefore, there is no evidence of structural similarity to a ref. compound(s) known to have a particular therapeutic or pharmacological utility as being supportive of an assertion of therapeutic utility for instantly claimed new compounds. In re. Jolles, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980). MPEP 2103.03.

12. Applicants recite that the instant compounds had at least an IC50 of less than 50nM in vitro models in specification pages 216-218. The expressions "biological activity" and "biological properties" are too nebulous to meet the requirements of 35 U.S.C. 112. In re Kirk et al. (CCPA 1967) 376 F2d 936, 153 USPQ 48. The " how to use" requirements of 35 USC 112 are not met by disclosing only a pharmacological activity of the claimed compounds if one skilled in the art would not be able to use the compounds effectively without undue experimentation. In re Diedrich (CCPA 1963) supra; In re Gardner et al. (CCPA 1970) 427 F2d 786, 166 USPQ 138.

13. Applicants attention is drawn to the fact that a disclosure in an application, to be complete, must contain such description and details as to enable any person skilled in the art or science to which the invention pertains to make and use the invention as of its filing date. In re Glass, 492 F.2d 1228, 181 USPQ 31 (CCPA 1974). See also MPEP 608.01(p).

14. The method of use claims12, 14,16,17, 19-42 do not represent exactly a single specific organ related disease in a subject, which could be a human being.

Conclusion

Allowable Subject Matter

15. Claims1-4, 6-8, 10,11 related to compounds and simple composition of the elected invention of Group II would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, objections, and other rejections, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

16. The following is a statement of reasons for the indication of allowable subject matter: The closest prior art ref. Schindler et al (WOOOO2851) teaches compounds having a core:"Heterocycle-SO2-Phenyl-NHCO-pyridine-2-NH-SO2-phenyl" The ref. '851 does not indicate or suggest to arrive at the compounds of amended claims having a core:" Heterocycle-Alkyl-phenyl-NHCO-pyridine-2-amino-CH2-phenyl".

17. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhaker B. Patel, D.Sc.Tech. whose telephone number is 703 308 4709. The examiner can normally be reached on 6:30 to 5:00 pm (Monday-Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Mukund J. Shah can be reached on 703 308 4716 or Sr. Examiner Mr. Richard Raymond at (703) 308 4523.

The fax phone numbers for the organization where this application or proceeding is assigned are 703 308 4556 for regular communications and 703 308 4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 1235.

Sudhaker B.Patel, D.Sc.Tech.
November 6, 2003.

MUKUND SHAH
SUPERVISORY PATENT EXAMINER
ART UNIT 1624